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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,168

06/29/2006

Nathalie Norais

PP019737.0004

5751

27476

7590

03/01/2010

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY- X100B

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Emeryville, CA 94662-8097

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

03/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,168

Applicant(s)

NORAIS ET AL.

Examiner

Patricia A. Duffy

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

RESPONSE TO AMENDMENT

The amendment filed 11-25-09 has been entered into the record. Claims 4-5 have been cancelled. Claims 1-3 and 6-13 are pending. Claims 9-13 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 1-3 and 6-8 drawn to an invention nonelected with traverse in the response filed 4-23-09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

The rejection of claim 13 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn based on Applicants amendment to the claims.

Rejections Maintained

Claims 9-11 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (WO200277183, 03-October 2002) in view of Harlow and Lane (Antibodies a Laboratory Manual, Cold Spring Harbor Laboratory, Chapter 5, pages 53-137, 1989.) is maintained for reasons made of record in the Office Action 8-27-09.

Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (WO200277183, 03-October 2002) and Harlow and Lane (Antibodies a Laboratory Manual, Cold Spring Harbor Laboratory, Chapter 5, pages 53-137, 1989) as applied to claims 9-11 and 13 above and further in view of Telford et al (WO 02/34771, May 2, 2002) is maintained for reasons made of record in the Office Action 8-27-09.

Claims 9-11 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tettelin et al (Science, 287:1089-1805, 2000; of record on 1449) in view of Harlow and Lane (Antibodies a Laboratory Manual, Cold Spring Harbor Laboratory, Chapter 5, pages 53-137, 1989) and Campbell (Monoclonal Antibody Technology, Chapter 1 pages 1-32, Elsevier Science Publishing Company, Inc., 1986, section 1.3.4) is maintained for reasons made of record in the Office Action 8-27-09.

Claim 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tettelin et al (Science, 287:1089-1805, 2000; of record on 1449), Harlow and Lane (Antibodies a Laboratory Manual, Cold Spring Harbor Laboratory, Chapter 5, pages 53-137, 1989) and Campbell (Monoclonal Antibody Technology, Chapter 1 pages 1-32, Elsevier Science Publishing Company, Inc., 1986, section 1.3.4) as applied to claims 9-11 and 13 above and further in view of Telford et al (WO 02/34771, May 2, 2002) is maintained for reasons made of record in the Office Action 8-27-09.

Inasmuch as the art rejections were traversed together, they are rebutted together. Applicant's arguments have been carefully considered but are not persuasive. Applicant repeatedly argues the incorrect statute over the combinations of Wang et al or Tettelin et al. The rejections have been made under 35 USC 103 and not 35 USC 101. As such, the arguments with respect to specific and substantial or real world utility are not persuasive on their face. The protein disclosed by Wang et al is 99.2% identical as compared with SEQ ID NO:207.

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Query Match          99.2%; Score 1986; DB 1; Length 389;
Best Local Similarity 99.0%; Pred. No. 1.le-188;
Matches 385%; Conservative 1; Mismatches 3; Indels 0; Gaps 0;

ly      1 MSEYLFTSSEVSEGHDPKVADQVSDAILDAILAQDPKARVA AETLVNTGLCVLAGEITTT 60
      |||
lb      1 MSEYLFTSSEVSEGHDPKVADQVSDAILDAILAQDPKARVA AETLVNTGLCVLAGEITTT 60

ly      61 AQVDYIKVARETIKRIKIGYNSSELGFDANGCAVGYYDQQSPDIAQGVNEGE GIDLNOGAG 120
      |||
lb      61 AQVDYIKVARETIKRIKIGYNSSELGFDANGCAVGYYDQQSPDIAQGVNEGE GIDLNOGAG 120

ly      121 DQGLMFGYACDETP TLMFPAIYYSHRLMQRQSELRKDGRLPWLRPDAKAQLTVVYDSETG 180
      |||
lb      121 DQGLMFGYACDETP TLMFPAIYYSHRLMQRQSELRKDGRLPWLRPDAKAQLTVVYDSETG 180

ly      181 KVKRIDTIVVLSTQHDP SIAVEELKNNAVIEHIKPVLPSELLTDETKYLINPTGRFVIGGP 240
      |||
lb      181 KVKRIDTIVVLSTQHDP SVGYEELKNNAVIEHIKPVLPSELLTDETKYLINPTGRFVIGGP 240

ly      241 QGDCGLTGRKIIIVDTYGGAAPHGGA FSGKDP SKVDRSAAYACRYVAKNIVAAGLATQCQ 300
      |||
lb      241 QGDCGLTGRKIIIVDTYGGAAPHGGA FSGKDP SKVDRSAAYACRYVAKNIVAAGLATQCQ 300

ly      301 IQVSYAIGVAEPT SISISIDTFGTGKISEEKLIALVREHFDLRPKGIVQMLDLRLPIYSKSA 360
      |||
lb      301 IQVSYAIGVAEPT SISISIDTFGTGKISEEKLITLVREHFDLRPKGIVQMLDLRLPIYSKSA 360

ly      361 AYGHFGREEPEFTUERTDKAAALRAAAGL 389
      |||
lb      361 AYGHFGREEPEFTUERTDKAAALRAAAGL 389
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The protein of Tettelin et al is 100 % identical as compared with SEQ ID NO:207.

Bacterial proteins have a plethora of uses and bacterial proteins are used in the art to make antibodies for detection of infection by many different methodologies including western blotting. Unlike Applicant's narrow interpretation of bacterial and antigen detection, there is no need for the protein to be expressed on the surface of a bacterium to be detected in western blotting or for the released antigen to be detected in a sample. Applicants argue specificity and sensitivity of antibodies to essential proteins such that one skilled would not select any of these proteins. This is also not persuasive the claims are drawn to immunogenic compositions comprising proteins, the immunogenic compositions are simple and straight forward to make and one would have been motivated to make antibodies for the disclosed uses as combined and articulated in the rejections. The art

clearly establishes why one would want to make antibodies and even acknowledge (see Campbell of record) that one would make such even without a clear motivation for doing so. There is motivation provided to make immunogenic compositions in order to make antibodies in each of the 103 rejections to each of the proteins disclosed in Wang et al and Tettelin et al and such is clearly enabled.

The rejection is maintained.

Status of Claims

Claims 9-13 stand rejected. Claims 1-3 and 6-8 are withdrawn from consideration.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner